(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
DRAFT/ MINUTES OF BOARD MEETING

December 15, 2010
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:12 AM.

PRESIDING: Brandon Yi, Chairman

MEMBERS PRESENT:
Gill B. Abernathy
Jody H. Allen
John O. Beckner
Gerard Dabney
David C. Kozera
Robert M. Rhodes
Leo H. Ross
Ellen B. Shinaberry
Pratt P. Stelly

STAFF PRESENT:
Caroline D. Juran, Acting Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Dianne L. Reynolds-Cane, Director, DHP
Arne Owens, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

QUORUM: With ten members present, a quorum was established.

APPROVAL OF AGENDA: With no changes to the agenda, the agenda was approved as presented.

APPROVAL OF MINUTES: The Board reviewed draft minutes for September 8, 2010 (board meeting); September 8, 2010 (panel formal hearings); September 21, 2010; September 28, 2010; October 28, 2010; November 17, 2010; and December 2, 2010. With no changes to the minutes, the minutes were approved as presented.

PUBLIC COMMENTS: There were no public comments offered at this time.

DHP DIRECTOR'S REPORT: Dr. Dianne L. Reynolds-Cane discussed the state of the agency, highlighting accomplishments and challenges during the past year. As Director, Dr. Cane participated as an advisor to the Reform Health Council, served on the State Lyme Disease Taskforce, and participated with the National Drug Take-back Program and the Homeless Advisory Committee. Additionally, she briefly stated

that fiscal matters are currently under review due to an uncontrollable increase in fees from Northrop-Grumman/Virginia Information Technologies Agency. Other highlights over the past year included: the Administrative Proceedings Division having closed 640 disciplinary cases; the Health Practitioners' Monitoring Program having accepted 102 participants; and the Prescription Monitoring Program having doubled the number of registered users and quintupled the number of requests for information. She concluded by announcing that second-round interviews for the Executive Director position of the Board of Pharmacy would be held in the near future and a hiring decision would be made by the end of January 2011.

LEGISLATION:

- Legislation update

Ms. Yeatts reported that multiple bills have already been filed to add synthetic marijuana to Schedule I for the upcoming General Assembly. Additionally, she stated that the Board's legislative proposal to add tramadol and carisoprodol to Schedule IV and conform state law to federal rule by adding immediate precursors of amphetamine, methamphetamine, phencyclidine, and fentanyl to Schedule II had not been approved by the Governor. She added that it's possible that another legislator could choose to introduce similar language, but that the proposal would not be included in the Governor's package. She further stated that she anticipated the submission of a bill to amend the requirement passed in 2010 regarding proof of identity when picking up a dispensed Schedule II drug.

REGULATIONS:

- Regulation update

Ms. Yeatts reported that the emergency regulations authorizing the repackaging of certain dispensed drugs within a community service board or behavioral health authority have been signed by the Governor and will be effective December 20, 2010 to December 19, 2011. Public comment on the notice of intended regulatory action for permanent regulations will close on February 2, 2011. Additionally, Ms. Yeatts reported that the following fast-track regulations remain under administrative review: the signing of the delivery record for automated dispensing devices in hospitals; the addition of administrative fees; and, the elimination of an alarm system for certain emergency medical service agencies.

- PHARMACY INSPECTION PROGRAM:

Sammy Johnson, Assistant Director, Enforcement Division, provided an update on the recently revised routine pharmacy inspection process. He referenced the December 2010 Board e-newsletter article regarding the most commonly cited deficiencies

in community pharmacies; i.e., deficiencies regarding inventories, records for partial dispensings, records for filling automated counting devices, proper labeling of prescriptions, back-up for security systems, proper storage of emergency keys, and proper storage of drugs within refrigerators and freezers. He further stated that, for the 146 routine inspections of community pharmacies performed between July 1, 2010, and November 30, 2010, 51 inspections resulted in no cited deficiencies, 34 inspections resulted in a cited deficiency, and 61 inspections resulted in a cited deficiency with a monetary penalty. Additionally, he reported that 12 pilot inspections had been performed in pharmacies providing services to hospitals between July 1, 2010, and November 30, 2010, and that four inspections had resulted in a cited deficiency and eight inspections resulted in a cited deficiency that would have imposed a monetary penalty had it not been a pilot inspection.

Action Item:

Twelve pilot inspections had been performed in pharmacies providing services to hospitals, therefore, the Board determined that enforcement should continue piloting the inspections in this environment and would review the statistics at the March 2011 meeting for consideration as to whether to go "live" with the inspection program in the hospital/institutional environment. Additionally, regarding cited deficiencies for not properly reporting a drug loss to the Board, Gill Abernathy commented that confusion may exist for when a drug loss should be reported. After discussion, the Board agreed that staff should include an article in the next e-newsletter regarding the reporting requirements for the theft or loss of drugs.

GUIDANCE DOCUMENT REVISION:

- Guidance Document 110-9 Pharmacy Inspection Deficiency Monetary Penalty Guide

Ms. Juran reviewed possible changes to certain deficiencies listed in Guidance Document 110-9. It was decided that only those deficiencies that impact the community pharmacies would be reviewed for amendment, since the inspection program will continue to perform pilot inspections of pharmacies that provide services to hospitals and other institutions. There was discussion regarding increasing the number of minor deficiencies that must be cited, from three to five, prior to the imposition of a $250 monetary penalty as a means of decreasing the number of pre-hearing consent orders issued. However, Ms. Juran reported that this change would not have an overall impact on whether the inspection resulted in the issuance of a pre-hearing consent order. Statistics indicate that most pre-hearing consent orders involve the citing of a major deficiency which automatically imposes a monetary penalty and the issuance of a pre-hearing consent order. Thus, the Board agreed

that no amendment was necessary.

For major deficiency #8, the Board agreed to the condition that the temperature may be "determined using inspector's or pharmacy's calibrated thermometer".

For major deficiency #9, Ms. Juran stated that, thus far, if a pharmacy alarm was incapable of sending an alarm signal to the monitoring entity when breached if the communication line was not operational, then the pharmacy was cited with this deficiency and a $1,000 monetary penalty was imposed. There was discussion regarding creating a separate major deficiency for this requirement with a reduced monetary penalty since the alarm system was otherwise operational and being set. The Board agreed to create a new major deficiency, #9a, "Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational" with a monetary penalty of $250.

For major deficiency #13, the Board agreed to modify the language as "No biennial inventory, or over 30 days late or substantially incomplete; i.e., did not include all drugs in Schedules II-V, or a physical count was not performed".

For major deficiency #14, the Board agreed to modify the language as "No incoming change of PIC inventory taken within 5 days or substantially incomplete; i.e., did not include all drugs in Schedules II-V, or a physical count was not performed".

For major deficiency #15, there was discussion as to whether the Board should implement a 10% threshold for determining compliance with the perpetual inventory requirement. It was determined that the perpetual inventory requirement aided the detection of diversion and that a threshold should not be implemented.

Motion: **The Board voted unanimously to amend guidance document 110-9 as follows:**

major 8, the Board agreed to the condition that the temperature may be "determined using inspector's or pharmacy's calibrated thermometer";

major 9a was added to read "Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational" and states a suggested monetary penalty of $250;

major 13 was modified to read "No biennial inventory, or over

30 days late or substantially incomplete; i.e., did not include all drugs in Schedules II-V, or a physical count was not performed"; and,

major 14 was changed to read "No incoming change of PIC inventory taken within 5 days or substantially incomplete; i.e., did not include all drugs in Schedules II-V, or a physical count was not performed". (motion by Kozera, second by Dabney)

UPDATE ON ACTION ITEMS:

- Reporting of disciplinary action to NPDB-HIPDB

Per the Board's request at the September meeting, Ms. Juran reported that she had researched whether other states were reporting disciplinary action taken against a facility permit to NPDB-HIPDB and whether reported disciplinary action taken against a facility permit would jeopardize a contract to receive government funds. She referenced a survey recently performed by the Texas Board of Pharmacy which indicates that of the 25 states responding to the survey, 19 states report action taken against a pharmacy and 6 do not. Additionally, she stated that on October 13, 2010, she participated in a telephone conference call with Regina Keegan, Policy Analyst, NPDB-HIPDB, SRA International, Inc. During the conference call, Ms. Keegan explained that other states have been reporting facility-related disciplinary action since 1992 and that she is not familiar with an instance wherein a pharmacy was denied a government contract due to a reported action. Ms. Keegan further explained that a state is required to report action involving an administrative fine that is connected to health care delivery. Because many of the possible deficiencies resulting from a routine inspection may be construed to be connected to health care delivery and the agency's policy is to report all publicly available disciplinary actions taken by the Board to NPDB, HIPDB, and Section 1921, these disciplinary actions shall continued to be reported.

- Survey of other states' filing requirements regarding "on-hold" prescriptions

Per the Board's request from the September meeting, Ms. Juran requested NABP to send an electronic survey of specific questions to the other states to solicit information on their rules or policies for filing "on-hold" prescriptions. Fourteen states responded and a summary of responses was provided in the agenda packet. Only two states addressed the handling of "on-hold" prescriptions in rule. However, the survey results indicated that there is some concern for the potential of pharmacists not verifying the data entry of an on-hold prescription which could and has led to dispensing errors. The Board members shared this concern. Additionally, as follow-up to the September meeting, Ms. Juran reported that she had contacted Mark Caverly, Chief, Liaison and Policy Section, Office of

Diversion Control, Drug Enforcement Administration, who confirmed that federal law and regulation do not directly address whether a prescription shall be filed by date of initial dispensing or initial entry into the pharmacy electronic record keeping system. Therefore, it was determined that an ad-hoc committee should be appointed to consider the need for regulatory action regarding the requirements for data-entry of on-hold prescriptions, pharmacist verification of the accuracy of the entered data, and the filing of these prescriptions.

Motion:

The Board voted unanimously to the formation of an ad hoc committee to consider the need for regulatory action regarding the requirements for data-entry of on-hold prescriptions, pharmacist verification of the accuracy of the entered data, and the filing requirements for these prescriptions, and to appoint John Beckner, Robbie Rhodes, Jody Allen, David Kozera, and Brandon Yi to this committee. (motion by Beckner, second by Dabney)

MISCELLANEOUS:

- Sanctioning Reference Points Training

The Board of Health Professions has recently requested that Kimberly Langston and Neil Kauder from VisualResearch, Inc. provide training to the various boards on the sanctioning reference points. This training is periodically provided to afford new board members an opportunity to learn of this tool and ask questions of these experts. Ms. Langston was present and reviewed with the Board that sanctioning reference points is a tool for the Board to use to increase consistency in disciplinary matter outcomes. Ms. Langston also reviewed a "Sample Case" with the Board.

REPORTS:

- Report on Collection of Data and Information about Utilization of the Prescription Monitoring Program pursuant to SJR 73 and SJR 75 (2010)

Ralph Orr, Program Director of Virginia's Prescription Monitoring Program (PMP), gave an overview of the program's report submitted to the General Assembly as required by SJR 73 and SJR 75. Mr. Orr thanked the Board for the opportunity to present information about the report and then gave a brief description of the Advisory Panel which was instrumental in helping develop the report and recommendations.

Mr. Orr stated that there were seven specific questions to which the program was asked to respond. He then provided highlights of the responses to each of the questions. Overall, the PMP has seen exceptional growth since the implementation of 24/7 access which resulted from the implementation of auto response software in October 2009. The number of registered users has doubled and the number of reports processed quadrupled from the previous year. At

the same time, data indicates a possible effect at reducing the number of patients seeking care from multiple prescribers and pharmacies in the first six months of 2010 compared to previous data.

Recommendations for enhancing the PMP were also requested to be included in the report to the General Assembly. Mr. Orr explained that most of the recommendations are specifically related to meeting minimum eligibility requirements for federal grant funding. There is no proposed legislation or regulatory action being initiated at this time that is related to these recommendations.

Mr. Yi asked for an update of the 2009 security breach and Mr. Orr provided basic background information. Mr. Orr stated that the breach is still an ongoing criminal investigation being conducted by federal and state law enforcement. Mr. Orr explained that the PMP had been. The program software and database were scheduled to move to a new facility with new software and equipment 30 days after the breach that occurred on April 30, 2009, and are now housed in the Commonwealth's CESC facility using state-of-art network security.

Mr. Beckner asked if pharmacists and prescribers can receive information from other states' PMPs. Mr. Orr stated all of Virginia's border states with PMPs (does not include Maryland and Washington, DC) currently allow pharmacists and prescribers in Virginia to register to use their programs. Currently, a user has to have multiple accounts and make separate requests to receive prescription information from the various state programs. There is an effort underway that will allow a user in Virginia to receive information from the Virginia PMP and from other state programs with which there is an agreement for sharing information while only needing to have an account with Virginia's PMP. The system will be easy to use once in place. A user will simply indicate from which state programs (from those available) information is needed and the receiving of the report will occur much as it does now. This feature should become available in a limited format in late 2011.

At approximately 12:00, Ms. Abernathy departed from the meeting.

- Report on NABP Member Forum Meeting

John Beckner reported on his attendance at the NABP Member Forum Meeting held on September 22-23, 2010 in Mount Prospect, Illinois. He stated the meeting was an opportunity for members of other state boards and NABP staff to discuss concerns regarding relevant topics such as the use of pharmacy coupons, prescription drug abuse, and proper disposal of drugs. Further, he stated that the Meeting was worthwhile and his being able to meet both other state

board members and NABP staff was beneficial.

- Disciplinary Process Report

Ms. Reiniers-Day explained the four priorities used in the disciplinary process as well as the "no" priority. Further, she explained the use of status levels used and that, as of December 8, 2010, there were 152 docketed cases with 69 at the enforcement level, 48 at the probable cause level, two at the informal conference level, one at the OAG level and five at the formal hearing level.

- Acting Executive Director's report

Ms. Juran provided a summary of the two current Board-approved innovative (pilot) programs. The first involves pharmacy technicians at seven pharmacies owned by Omnicare using bar-code scanning technology to perform the final verification check of bingo cards containing Schedule VI drugs. Terms and conditions are outlined in the consent order which include a requirement for pharmacists to verify the accuracy of 10% of these dispensings. To date, the required quarterly reports indicate no errors associated with this process. The second innovative (pilot) program waives the requirement in Regulation 18VAC110-20-555 which restricts the use of automated dispensing devices to nursing homes and authorizes The Pines, a residential environment for youth, to qualify for the use of these dispensing devices. The Pines uses only nurses to administer drugs and demonstrated a similarity to a nursing home environment. Ms. Juran also stated that a Board committee has reviewed and approved an application for the use of Instymeds technology which stores and prepares drugs for dispensing in a device similar to a vending machine, but that the applicant had withdrawn the application. Based on telephone calls received by Ms. Juran, she anticipates another application for the use of Instymeds to be submitted in the near future.

Ms. Juran then reported that the Board of Pharmacy is currently not represented on the Board of Health Professions ("BHP") and that the Executive Director of BHP advised that, at the September 29, 2010, Board Meeting, the Board finalized its studies on medication aide expansion into nursing homes, medical laboratory scientists and technicians, and kinesiotherapists. The request for a review of grand aides has been withdrawn due to a conflict with the nursing scope of practice laws. Additionally, the Board will continue to review developments relative to Community Health Workers as they are emerging to take on a greater role in filling support service gaps, especially in underserved areas, and it continues to review the need to create a Allied Health Board.

Ms. Juran announced that one bid had been received for the RFP to obtain an examination contractor for the Virginia Federal and State Drug Law Exam. Negotiations will begin in the near future. The contract for the current contractor ends June 30, 2010.

Ms. Juran attended the NABP District I and II meeting held on October 29-31, 2010, in Cooperstown, New York.. She stated that the focus of the meeting was information sharing to learn how other states are addressing current concerns. She felt Virginia was positioned well on most subjects relative to the other states in attendance, particularly regarding the use of collaborative practice agreements, administration of immunizations, and registration of pharmacy technicians.

Lastly, Ms. Juran provided the Board with a copy of a recent news release from the American Pharmacists Association which announced the renaming of the APhA Summer Internship Program to the Carl Emswiller Summer Internship in Association Management. It stated that a generous memorial fund had been established by his wife and it honors his contributions to the profession. Mr. Emswiller, who died in December 2009, co-owned and operated Emswiller Pharmacy in Leesburg, Virginia, received the Remington Honor Medal in 1999 from APhA, and served as a past chairman of the Board of Pharmacy.

NEW BUSINESS

There was no new business discussed.

RECOGNITION OF FORMER BOARD MEMBERS

During a working lunch, Mr. Yi and Elizabeth Scott "Scotti" Russell, the former Executive Director, presented plaques of recognition to the following former board members: Bobby Ison, Jennifer Edwards, and Michael Stredler. Willie Brown was not able to attend, but was recognized.

ADJOURN:

With all business concluded, the meeting adjourned at 1:30p.m.

Caroline D. Juran
Acting Executive Director

Brandon Yi, Board Chairman

Date

Date